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EXAMINER

JACOBSON, MICHELE LYNN

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## **DETAILED ACTION**

### ***Double Patenting***

1. Applicant's terminal disclaimer filed 1/22/08 has been accepted. The double patenting rejection is therefore withdrawn.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 9-14, 18-20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. U.S. Patent No. 7,011,872 (hereafter referred to as Ding).
4. Ding teaches a blend of 1,2 syndiotactic polybutadiene with a crystallinity of less than 50% and most preferably within the range of about 13% to about 40% for use in fabricating medical products such as tubings, pump compatible tubings (Col. 8, line 44), peritoneal dialysis administration sets (Fig. 4), I.V. administration sets (Fig. 5), drip chambers and the like. (Col. 3, lines 50-51, 61-66) Bonding together components made with the 1,2 syndiotactic polybutadiene polymer blends including an example of bonding a polybutadiene blend tube to a polybutadiene blend drip chamber is recited. (Col. 9, lines 41-47) The polymer blends and products made therefrom are disclosed to

be exposed to sterilization doses of electron beam radiation in the range from about 15 kGys to about 45 kGys. (Col. 5 line 65-Col. 6 line 2, Claim 22) Exposing the blend or product to radiation within this range is recited to cause a measurable change in the gel content of the blend or product which may increase the mechanical strength and prolong the time of service in a medical pump tubing application. (Col. 6, lines 9-18) A tubing made from the inventive composition of Ding is recited to be bonded to a rigid component such as a connector. (Col. 9, lines 28-30) An example of joining a polybutadiene tubing to a polybutadiene drip chamber both made of the polybutadiene compound of the invention is recited. (Col. 9, lines 44-47)

5. It is well known in the polymer art that varying the crystallinity of a polymer will predictably change the rigidity of the resulting polymer composition. Ding recites that the tubing comprising the 1,2 syndiotactic polybutadiene of the invention can be solvent bonded to a more rigid component (i.e. a drip chamber) comprised of the same material.

6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have produced a tubing with crystallinity in the lower region of the range recited by Ding and a rigid connector in the higher region of crystallinity recited by Ding in order to obtain the a flexible tubing as recited by Ding that could be attached to a connector with greater rigidity as recited by Ding. The application of well known teachings in the polymer art to Ding would have produced the invention as claimed in claims 1-4, 9-14, 18-20 and 23-25.

7. Regarding claims 1-8 and 23: The medical tubing with a crystallinity of about 5-25% solvent bonded to a drip chamber (i.e. connector) with a crystallinity of about 25-

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40% as claimed 1-4 and 23 would have been the result of the optimization of Ding as recited above.

8. Regarding claims 24 and 25: Depending on the amount of rigidity desired for the application of the 1,2 syndiotactic polybutadiene article it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected any crystallinity within the range recited by Ding. This selection of crystallinities would have produced the invention as claimed in claims 24-25.

9. Regarding claims 12-14: Ding explicitly teaches cross-linking of the medical member by electron beam radiation as recited in claims 12-14.

10. Regarding claims 9-11 and 18-20: Since the polymer blends, crystallinity and article treatments recited by Ding are the same as those recited by applicant, the medical member and connector of Ding would be expected to inherently exhibit the properties as claimed by applicant in claims 10-11 and 18-20. See MPEP 2112 V. Ding recites exposure to e-beam radiation, which results in cross-linking of the polymer increasing its melting point and making it inherently able to withstand steam sterilization. (Claims 9-11) Since Ding recites the same polymer blend as applicant, the amount of halogen would inherently be within the range cited in claims 18-20.

11. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. U.S. Patent No. 7,011,872 as applied to claims 1 and 12-14 above in view of Doheny Jr. U.S. Patent No. 5,063,005 (hereafter referred to as Doheny)

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12. Ding does not explicitly state the energy of the electron beam so that a product of the electron beam and dose may be calculated. The range of electron dose recited by Ding (less than 5 Mrad) falls within that recited by the applicant in the specification (1-100 Mrad).

13. Doheny, Jr. teaches electron beam irradiation of polyolefins to obtain a desired modulus. Doheny, Jr. teaches that needed radiation can be readily calculated by a skilled practitioner based upon dosage to effect the required cross-linking, such as line speed, kilovolts required to provide a penetrating potential and current (column 10, line 44, to column 11, line 2)

14. The motivation to combine Ding with Doheny would have been as Ding recites to provide cross-linking to “increase the mechanical strength and prolong the time of services in a medical pump tubing application”. (Col. 6, lines 16-18)

15. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Ding with Doheny in order to produce a medical tubing and connector made by electron beam dosing within the range disclosed by applicant. Since Ding discloses cross-linking of syndiotactic 1,2 polybutadiene from radiation exposure and the benefits it provides, it would have been obvious to and within the ability of one of ordinary skill to optimize the parameters disclosed by Doheny (such as dosage and energy) to obtain the invention as claimed in claims 15-17.

16. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. U.S. Patent No. 7,011,872 as applied to claims 1 and 2 above in view of Bacehowski et al. U.S. Patent No. 4,299,256 (hereafter referred to as Bacehowski).

17. Ding is silent regarding the addition of lubricant to the polymer blends used to make the medical tubing and connector of the invention.

18. Bacehowski teaches adding from 1 to 5 parts by weight of silicone oil to the polymer blend of a tubing for use as roller pump tubing. (Col. 2, lines 8-10)

19. The motivation to combine Ding with Bacehowski would have been as Bacehowski recites to provide a permanently lubricated tubing surface "even when some of the surface is worn away by continued abrasion or friction, so that the tubing can have a greatly extended life under such conditions of abrasion or friction". (Col. 1, lines 23)

20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined Ding with Bacehowski in order to produce a syndiotactic 1,2 polybutadiene medical tubing with 10 parts or less of lubricant disposed therein as claimed in claim 21 and 22.

### ***Response to Arguments***

20. Applicant's arguments filed 1/22/08 have been fully considered but they are not persuasive. Applicant argues on page 7 of the remarks that Ding does not recite using separate crystallinity values for the tubing and connector as claimed in amended claim

1. The new grounds of rejection cited by the examiner address this argument.

Although Ding does not disclose a tube and a connector with the specific crystallinities claimed by applicant it is the examiner's opinion that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the crystallinities recited in Ding in order to produce a flexible tubing a rigid connector as recited by Ding.

### ***Conclusion***

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE JACOBSON whose telephone number is (571)272-8905. The examiner can normally be reached on Monday-Thursday 8:30 AM-7 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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